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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,627	EULENBERG ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *2-7,10,14-24,26,28-30 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8, 9, 11-13, 25, 27, 31, 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/18/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1653.

Applicants' response to Restriction Requirement filed on June 22, 2006 is acknowledged. Applicants have elected group X(ii), claims 25, 27 and 33 with traverse. Applicants have also elected CG7956 (synaptojanin-like protein SAC) as the polypeptide. The traversal is on the ground(s) that group I(viii) should be examined together with group X(ii). Group I(viii) is directed to a pharmaceutical composition comprising a CG7956 polypeptide and thus is the composition used in the claims of group X(ii). The reasons for traversal are fully considered and found persuasive. Claim 27 requires use of a polypeptide of claim 1 directly for the preparation of a medicament for treatment and not drawn to the same polypeptide of claim 25 or 33. It should be noted that group X(ii) requires further restriction to X(ii a) claims 25 and 33 and X(ii b), claim 27 because the polypeptide of claim 25 and 33 have different structure and function from the polypeptide of claim 27 thus they are patentably distinct. In the restriction requirement (May 22, 2006) claims 25 and 33 were joined with claim 25 inadvertently. Regarding the species election Applicants have elected diabetes as the disorder.

Claims 1, 8, 9, 11-13 and 31 of Group I(viii) are rejoined insofar as they read on CG7956 polypeptide.

Claims 2-7, 10, 14-24, 26, 28-30 and 32, have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Therefore, claims 1, 8, 9, 11-13, 25, 27, 31 and 33 are under examination on the merits.

The restriction requirement still deemed proper and is therefore made FINAL.

Objection to the Specification

The disclosure is objected to because of the following informalities:

1) The continuity data needs to be updated.

2) The drawings are also objected to because of the following informalities:

ln Figures 1, 2, 4, 5, 6, 8-10, 12-14, 16-18, 20-22, 24-26 and 28, the description of the drawings in the legend belongs in the brief description of the drawings section in the disclosure. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Appropriate correction is required.

3) The specification is objected to for improper disclosure of a multitude of amino acid and or nucleic acid sequences without a respective sequence identifier, i.e. a SEQ ID NO. For example, Figures 3, 7, 11, 15, 19, 23 and 27 include sequence disclosures and the brief description of said figures does not include respective SEQ ID NOs. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. ln the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any

amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

Objection to the Claims

The claims are objected to because of the following informalities:

1) Claims 1 and 31 are objected to as being drawn to non-elected subject matter.

2) Claims 1 is encompassing non elected elements, such as "effector/modulator."

3) Claims 25 and 33 are dependent on non-elected claims 20 and 21 respectively.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8, 9, 11-13, 25, 27, 31 and 33 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim is drawn to a pharmaceutical composition comprising a polypeptide encoded by CG7956 nucleic acid molecule and/or a functional fragment thereof, for the treatment of metabolic diseases, such as diabetes. However, the skilled artisan cannot necessarily envision the detailed structures of all the variants and or fragments of CG7956 that have functional activity the same as the wild-type CG7956 because nowhere in the specification is it described which amino acids are essential and critical for the wild-type protein to maintain its functionality, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the methods of making the claimed invention. The compound itself is required.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case the quantity of experimentation would be large because of the nonspecificity of the starting material as well as the unspecified number of mutations necessary. The amount of guidance in the specification is zero with regard to which amino acids in CG7956 are essential for activity. No working examples are present for the method and composition comprising the CG7956 proteins or fragments or variants thereof which can be used for treatment or prevention of diseases. The nature of the invention is such that many different proteins that are substantially similar to CG7956 may or may not have biological activity. The state of the prior art is that even proteins that are 99.99% similar to the wild-type protein are at times not fully active; then how with only 52% homology of human Sac domain-containing inositol phosphatase (SAC2, also referred to as KIAA0966 protein; NP_055752) protein, which is a human homolog of the gene product of Drosophila Accession Number CG7956 protein would enable the invention (see page 55 and Table 1 of the specification). The relative level of skill in this art is very high. The predictability as to what substantially similar protein will have which activity is zero.

When the factors are considered in their entirety, the Wands analysis dictates a finding of undue experimentation and thus, the claim is not enabled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 and dependent claims 8, 9, 11-13, 27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term "preferably" that renders the claim indefinite because the claim encompassed by "preferably," include(s) elements not actually disclosed thereby rendering the scope of the claim(s) unascertainable. See MPEP§ 2173.05(d). Claims 8, 9, 11-13 and 27 are included in the rejection because they are depending on a rejected base claim.

Claim 27 provides for the use of a polypeptide for the preparation of a medicament, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 27 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 11 and 12 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al. (DNA Research, Vol. 6 (1), pp 63-70, 1999).

Nagase et al. teach the complete sequences of 100 new cDNA clones from human brain which code for large proteins *in vitro*. The corresponding genes were named as KIAA0919-KIAA1018. Nagase's KIAA0966 is 4924 bp in length with corresponding open reading frame (ORF) of 1132 amino acid residues (see abstract, Fig. 1, Table 1). KIAA0966 DNA has 99.1% sequence identity to nucleic acid sequence of cDNA NM_014937, which is a human homolog of Drosophila gene Accession NO: CG7956 (see sequence alignment data of NM_014937, result 3, Database: GenEmbl, Accession NO: AB023183), and the KIAA0966 polypeptide encoded by the KIAA0966 cDNA has 100% sequence identity to amino acid sequence of protein Sac domain containing inositol phosphatase2 (SAC2) in Accession NO: NP_055752. SAC2 is a human homolog of Drosophila gene Accession NO: CG7956 (see sequence alignment data of NP_055752, result 2, Database: GenEmbl, Accession NO: AB023183, frame search), also see Table 1 at page 55 of the specification. The cDNA of Nagase's KIAA0966 has been sequenced thus the DNA has been dissolved in water or in a suitable buffer for sequencing. Thus composition of KIAA0966 in water or buffer is considered for the composition of claim 27 of the instant application. Since Nagase's KIAA0966 protein has 100% sequence identity to SAC2 protein of instant application, the composition containing KIAA0966 protein of Nagase must also be able to use for diagnostic composition (claim 11) and therapeutic composition (claim 12). Further the composition containing KIAA0966 protein must also be able to use for the

preparation of a medicament for the treatment and/or prevention of metabolic diseases or dysfunctions, thus anticipating claim 27 of instant application.

Conclusion

No claim is allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita Mitra, Ph.D.
August 2, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER